

REMARKS

I. Status of the Application

Claims 1-43 are presently pending in the application. Claims 8, 9, 16, 17, 19-21, 26, 33, 34 and 41-43, which have been withdrawn by the Examiner as being directed to a non-elected invention, have been cancelled without prejudice to the filing of any appropriate continuation applications. Claims 2-7, 11-13, 22, 24, 27-32 and 35-40 have been cancelled without prejudice to the filing of any appropriate continuation applications. Claims 1-7, 10-15 and 22-24 stand rejected under 35 U.S.C. §101 as provisionally being anticipated by copending Application No. 09/977,886. Claim 18 stands rejected under the judicially created doctrine of obviousness-type double patenting over copending Application No. 09/977,886. Claims 1-7, 10-15, 18, 27-32 and 35-40 stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. Claims 1, 10, 14, 18 and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Rhine et al. (1999) *J. Perinatol.* 19:206, or Notter et al. (1986) *Exp. Neurol.* 94:670. Claims 1, 10, 15, 18 and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sima et al. (1980) *Folia Microbiologica* 25:483. Claims 1-3, 6 and 22-24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Janes et al. (1995) *J. Clin. Invest.* 95:2581, or Haga et al. (1996) *Digest. Diseases Sci.* 41:1468. Claims 27-28 and 31 stand rejected under 35 U.S.C. §102(b) as being anticipated by Janes et al. or Haga et al. in view of Phelan et al. (1998) *Arch. Biochem. and Biophys.* 357:155. Claims 27, 31, 32, 35, 39 and 40 stand rejected under 35 U.S.C. §102(b) as being anticipated by Rhine et al., Notter et al. or Sima et al. in view of Phelan et al. Claims 7, 15 and 32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Janes et al. or Haga et al.

Applicant gratefully acknowledges the Examiner's indication that the promotion of differentiation in colon adenocarcinoma, lipocarcinoma, thyroid carcinoma and lymphoblast

cells is allowable subject matter. In response, Applicant has amended the pending claims to recite methods for promoting cell differentiation, wherein the cell is selected from the group consisting of liposarcoma cell, thyroid carcinoma cell and lymphoblast cell.

Support for the claim amendments can be found throughout the specification and claims as originally filed. Support for promoting cell differentiation can be found in claim 11 as originally filed which recites “promotes cell differentiation,” and in the specification at least at page 97, line 21, where Applicant teaches the induction of differentiation. Support for liposarcoma cells, thyroid carcinoma cells and lymphoblast cells can be found in the specification at least at page 105, lines 18-19, where Applicant teaches liposarcoma, thyroid carcinoma and lymphoblast cells, and at page 108, lines 1-2 where Applicant teaches inducing differentiation. The amendments presented herein add no new matter.

Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

II. Double Patenting Rejections

At page 2, paragraph 6 of the instant Office Action, claims 1-7, 10-15 and 22-24 stand provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-7, 10-15 and 20-24 of copending Application No. 09/977,866. At page 3, paragraph 4 of the instant Office Action, claim 18 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 09/977,866.

Applicant respectfully traverses these rejections in view of the amended claims presented herein. As amended, the instant claims are directed to methods of, and pharmaceutical

preparations for, promoting differentiation of a cell selected from the group consisting of liposarcoma cell, thyroid carcinoma cell and lymphoblast cell. In contrast, the pending claims in copending Application No. 09/977,866 have been amended such that they are directed to methods of, and pharmaceutical preparations for, promoting cell differentiation in a colon adenocarcinoma cell. Thus, the pending claims are distinct in scope from the pending claims of the '866 Application. Accordingly, Applicant respectfully requests that these rejections be reconsidered and withdrawn.

III. The Pending Claims Are Enabled

At page 4, paragraph 2 of the instant Office Action claims 1-7 and 27-32 stand rejected under 35 U.S.C. §112, first paragraph as lacking enablement. The Examiner is of the opinion that the specification does not reasonable provide enablement for promoting cell proliferation. Applicant respectfully traverses these rejections.

Without acquiescing to these rejections, Applicant submits that claims 2-7 and 27-32 have been cancelled without prejudice to the filing of any appropriate continuation applications to facilitate allowance of the case. Claim 1 was amended to recite a method of promoting cell differentiation and does not recite promoting cell proliferation. Accordingly, Applicant respectfully submits that this rejection has been rendered moot and requests that these rejections be reconsidered and withdrawn.

At page 5, paragraph 1 of the instant Office Action claims 3-4 and 28-29 stand rejected and at page 6, paragraph 1 of the instant Office Action, claims 5 and 30 stand rejected under 35 U.S.C. §112, first paragraph as lacking enablement. The Examiner is of the opinion that the

specification does not reasonably provide enablement for promoting inhibition or cell proliferation at concentrations of 10^{-8} M or less.

Applicant traverses these rejections and respectfully submits that the specification enables the claimed concentrations. Without acquiescing to these rejections, Applicant submits that in order to facilitate allowance of the case, claims 3-5 and 28-30 have been cancelled without prejudice to the filing of any appropriate continuation applications, thus rendering these rejections moot. Applicant notes that although claims 11-13 are directed to similar concentrations as claimed in rejected claims 3-5 and 28-30, claims 11-13 have not been similarly rejected. Applicant assumes an oversight on the part of the Patent Office. Accordingly, without acquiescing to the rejections of claims 3-5 and 28-30, Applicant submits that in order to facilitate allowance of the case, claims 11-13 have been cancelled without prejudice to the filing of any appropriate continuation applications

At page 7, paragraph 1 of the instant Office Action, claims 1, 10-15, 18, 27-32 and 35-40 stand rejected under 35 U.S.C. §112, first paragraph as lacking enablement. The Examiner is of the opinion that while the specification is enabling for promoting cell differentiation in colon adenocarcinoma, lipocarcinoma, thyroid carcinoma and lymphoblast cells, it does not reasonably provide enablement for promotion of differentiation in any other type of cell. Applicant respectfully traverses these rejections.

Without acquiescing to these rejections, Applicant submits that the pending claims have been amended to recite a method for promoting cell differentiation wherein the cell is selected from the group consisting of liposarcoma cell, thyroid carcinoma cell and lymphoblast cell to facilitate allowance of the case. As the Examiner has indicated that promoting cell

differentiation in lipocarcinoma, thyroid carcinoma and lymphoblast cells is enabled, Applicant respectfully requests that these rejections be reconsidered and withdrawn.

IV. The Pending Claims Are Novel And Nonobvious Over the Cited Art

At page 9, paragraph 1 of the instant Office Action, claims 1, 10, 14, 18 and 25 stand rejected under 35 U.S.C. §102(b) as anticipated by Rhine et al. (1999) *J. Perinatol.* 19:206, or Notter et al. (1986) *Exp. Neurol.* 94:670. Claims 1, 10, 15, 18 and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sima et al. (1980) *Folia Microbiologica* 25:483. Claims 1-3, 6 and 22-24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Janes et al. (1995) *J. Clin. Invest.* 95:2581, or Haga et al. (1996) *Digest. Diseases Sci.* 41:1468. Claims 27-28 and 31 stand rejected under 35 U.S.C. §102(b) as being anticipated by Janes et al. or Haga et al. in view of Phelan et al. (1998) *Arch. Biochem. and Biophys.* 357:155. Claims 27, 31, 32, 35, 39 and 40 stand rejected under 35 U.S.C. §102(b) as being anticipated by Rhine et al., Notter et al. or Sima et al. in view of Phelan et al. Claims 7, 15 and 32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Janes et al. or Haga et al.

At page 13 of the instant Office Action, the Examiner indicates that “[t]he promotion of differentiation in colon adenocarcinoma, lipocarcinoma, thyroid carcinoma and lymphoblast cells by a claimed bilin appears to be neither anticipated nor obvious over the prior art” and is allowable subject matter.

While Applicant respectfully traverses the Examiner’s rejections of the claims as being anticipated by Rhine et al., Notter et al., Sima et al., Janes et al., Haga et al., Janes et al. or Haga et al. in view of Phelan et al., and Rhine et al., Notter et al. or Sima et al. in view of Phelan et al., and as being obvious over Janes et al. or Haga et al., Applicant has amended the claims to recite

methods and pharmaceutical formulations for promoting cell differentiation by a bilin wherein the cell is selected from the group consisting of lipocarcinoma cell, thyroid carcinoma cell and lymphoblast cell in accordance with the Examiner's indication of allowable subject matter. Accordingly, Applicant respectfully requests that these rejections be reconsidered and withdrawn.

V. Conclusion

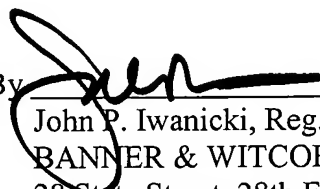
Having addressed all outstanding issues, Applicant respectfully requests entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

Dated: _____

April 8, 2024

By _____



John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
(617) 720-9600